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Allergy risks not properly assessed for a recently authorised GM maize, says EU expert

Shortcuts in EFSA's evaluation undermines their conclusions

Shortcomings in EFSA's evaluation

Strong disagreements are not common within EFSA's expert panels, and the agency's GMO panel in charge of evaluating potential impacts on health and the environment of GM plants to be authorised in the EU- is no exception. Yet, it is now the second time that Dr Jean-Michel Wal, who was until recently the panel's allergy expert, has expressed his doubts concerning so-called "stacked events" GMOs.

His new "minority opinion"[1], concerning GM maize Bt11 x MIR162 x 1507 x GA21 that expresses three insecticidal proteins (i.e. *Bt* proteins) is even more strongly worded than the 1st one (read our article on this issue). He expresses annoyance at the lack of progress concerning the shortcomings he highlighted already 18 months ago, and even notes lower vigilance from the panel[2].

"Stacked events" GM plants contain not only one genetic modification but several, each one making the plant produce a different new protein. This means that the evaluation has to take into account the potential risks posed by the interactions between these new proteins. However, this task is complicated by the fact that the authorisation must be delivered not only for the plant containing all the proposed events, but also all the possible sub-combinations. This means that in reality, it is not only one GM maize crop that is on the table, but more than 20 possible variations.

Incomplete data from the applicant

While this is is already disturbing, it becomes positively problematic when we learn that EFSA receives the data from the applicant (Syngenta in this case) on only some of the combinations, and that some of them have still not even been created.

For Jean-Michel Wal, "*it is not acceptable that the same weight and reliability are given to the assessment of a GM crop for which a complete data set is available and can be comprehensively evaluated and to GM crops for which no specific data are provided, particularly when there is a health concern*". Indeed, there is no

way to predict how the new proteins will be actually expressed because of the variability that is observed and that depends upon environmental conditions. In addition, it is perfectly possible for Syngenta to apply these modifications to another conventional maize variety in the future, which would potentially mean a different level and combination of expression of the new proteins in that future GM maize variety.

Extrapolating the available data to all the potential future creations therefore presents important limitations, which are completely ignored by EFSA's opinion in which no uncertainty analysis is performed, contrary to EFSA's general policy.

Allergic reactions in the rise in the EU

"*Allergic reactions in general and particularly food allergy are dramatically increasing in the EU (and worldwide) and have become a most important public health issue. The reasons are unclear, but most specialists involve the changes in environmental conditions, in cultivated plant species and in food habits",* explains Dr Wal. He also highlights the potential role of adjuvants, i.e. compounds present in food/diet that increase the immune response to other unrelated proteins present in the food. Some forms of *Bt* proteins are known to act as adjuvants and this expected unintended adverse effect of GM *Bt* maize cannot be simply disregarded when several types of them are expressed together at unknown concentrations.

For a long time, Dr Wal was ready to certify that GMOs were not responsible for this escalation of allergies, as the actual concentration of the few incriminated *Bt* proteins expressed in those GM plants was precisely determined and very low, but the shortcuts adopted by EFSA make him doubt he will be able to do the same in the future.

Dr Wal has now retired from the panel, but he still hopes that his calls for more research on the issue and a more thorough evaluation of stacked event GM plants expressing several insecticidal proteins at the same time will be heard. As for maize Bt11 x MIR162 x 1507 x GA21 (resistant to the maize borer *Ostrinia nubilalis*), it has been authorised at the beginning of August 2018 by the EU Commission for use in food and feed in the EU, despite the opposition of two thirds of the members of the European Parliament.

A new stacked events GM maize under discussion

As legislators, we have to wonder why the EU Commission seems so intent on authorising a new set of GM maize varieties which are not needed by the EU food and feed industry, are not even currently intended for such use by the applicants, were not properly evaluated and don't have sufficient political support.

This new debatable way of evaluating and authorizing GMOs seems to have become the rule, as another stacked events maize was proposed for authorization for import by the European commission recently (maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122). The environment committee of the European Parliament voted today an objection to its authorisation with a comfortable majority[3], mentioning among other reasons the serious concerns over the shortcomings of the assessment process. Both the plenary of the European Parliament and the member states are set to vote on this next week. Let us hope that they will manage to stop this new example of health and environmental carelessness.

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[1] A minority opinion is the framework in which the member of a panel can express their disagreement with the conclusions of an EFSA panel

[2] Assessment of maize Bt11 x MIR162 x 1507 x GA21 and sub-combinations, Appendix B - Minority opinion (p32)

[3] It also objected to the renewal of the authorization of GM maize NK603 × MON 810

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